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HARNESS, DICKEY & PIERCE, P.L.C. P.O. BOX 828 BLOOMFIELD HILLS, MI 48303				
			EXAMINER	
			BACHMAN, LINDSEY MICHELE	
			ART UNIT	PAPER NUMBER
			3734	
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			06/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/784,031

Applicant(s)

SCHAFFHAUSEN, CORY

Examiner

Lindsey Bachman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-7,20 and 22-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-7,20 and 22-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to Applicant's after final amendment filed on 5 June 2007.

Response to Arguments

Applicant's arguments with respect to claims 1-7, 20 and 22-32 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. **Claim 1-7, 20, and 22-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Sikora et al. (US Patent Application 2002/0019649) in further view**

of Oberlander (US Patent 5,702,462) and Bojarski et al (US Patent Application 2003/0130694).

2. Sikora'649 teaches a method for closing a tissue wound that includes inserting a needle (1070) containing a retaining head (1012) from a first insertion position (1060a) on a first outer surface of the body tissue, through the tear (1052) and to a second outer surface (1058) of the body tissue; ejecting the retaining head (1012) from the needle (1070) wherein the retaining head (1012) grasps the second outer surface (1058) in an engaged position (paragraph [0152]); advancing an anchor (1014) coupled to the retaining head (1012) (paragraph [0147], lines 1-2) from a second insertion position (1060b) on first outer surface of the body to a position through a portion of the tear (1052) (paragraph [0153]), said anchor (1014) coupled to the retaining head by a flexible member that extends a distance along the first outer surface of the body tissue from said first insertion position to said second insertion position (see Figure 1, element 10b).

3. Sikora'649 does not teach that the anchor is placed between the tear and the outer portion of the body tissue. Further, Sikora'649 does not teach that the retaining head and anchor are attached by the terminal end of the flexible member.

4. Oberlander'462 teaches that an anchor (11b) is placed within the body tissue (31) in a location that is between a tear (31d) and an outer portion of the body tissue (31b) (see Figures 5, 8 and 9) because this is said to enhance the repair of the body tissue since the anchor (11b) is implanted in the thicker part of the tissue (column 4, lines 3-34).

Bojarski'694 teaches that it is known in a method of repairing a meniscus to have a retaining head (1005) and an anchor (1010) that are attached at the terminal ends of a suture (1097) because it allows the surgeon to create tension in the suture by placing the retaining head and anchor a certain distance apart (paragraph [0151]-[0155]). This tension also causes the retaining head and anchor to shift to a direction that is perpendicular to the suture and apposes the meniscal tear. It would have been obvious to modify the method taught by Sikora'649 as taught by Bojarski'694 with a single suture that is attached by its terminal ends to a retaining head and anchor in order to create tension in the two anchors only by placing the terminal ends apart because this allows the surgeon to automatically tighten the suture without the need for the surgeon to additionally agitate and access the surgical site.

5. Regarding Claim 2, Sikora'649 teaches a method that includes ejecting the retaining head (1012) further includes advancing a plunger within the needle (1070) towards a distal opening of the needle, deploys the retaining head (1012) through the distal opening of the needle (1070), and removing the needle from the body tissue at opening first insertion portion (1060a) (see paragraph [0152]).

6. Regarding Claim 4, Sikora'649 teaches that advancing the anchor includes advancing a plunger within the hollow tube a predetermined distance towards the distal end in order to advance anchor (1014) to a desired location (paragraph [0153]).

7. Regarding Claim 3 and 5, Sikora'649 teaches a slit (1076) and attaching the flexible member to an appendage of anchor that protrudes through the slit and holding it while releasing the anchor (paragraph [0146]).

Regarding Claim 6, Sikora'649 teaches locating the distal end of the hollow tube (1070) a predetermined offset position (1060b) a predetermined offset position from the said first insertion position (1060a) and advancing the anchor to the desired location provides a taught flexible member between the first and second insertion positions (paragraph [0153]).

8. Regarding Claim 7, Sikora'649 teaches that ejecting the retaining head is performed simultaneously with advancing the anchor (paragraph [0150] and [151]).

9. Regarding Claim 20, Sikora'649 teaches a method of repairing a tear in a body tissue that includes a passing a needle (1070) from a first portion of the body tissue through the tear (1052) and to an outer surface of the body tissue (1058); ejecting a retaining head (1012) from the needle (1070) so that the retaining head (1012) lies against the outer surface (1058) in an engaged position (paragraph [0152]); and inserting an anchor (1014) coupled to the retaining head (1012) (paragraph [0147], lines 1-2) by a flexible member (1016) from a first portion through the tear to a desired location (paragraph [0153]).

10. Sikora'649 does not teach that the anchor is placed between the tear and the outer portion of the body tissue. Further, Sikora'649 does not teach that the retaining head and anchor are attached by the terminal end of the flexible member.

11. Oberlander'462 teaches that an anchor (11b) is placed within the body tissue (31) in a location that is between a tear (31d) and an outer portion of the body tissue (31b) (see Figures 5, 8 and 9) because this is said to enhance the repair of the body tissue since the anchor (11b) is implanted in the thicker part of the tissue (column 4,

lines 3-34). It would have been obvious to one skilled in the art at the time the invention was made to modify the method taught by Sikora'649 by placing the anchor between the tear and the outside of the body tissue because placing the anchor within the body tissue aids in enhancing the effectiveness of the repair.

Bojarski'694 teaches that it is known in a method of repairing a meniscus to have a retaining head (1005) and an anchor (1010) that are attached at the terminal ends of a suture (1097) because it allows the surgeon to create tension in the suture by placing the retaining head and anchor a certain distance apart (paragraph [0151]-[0155]). This tension also causes the retaining head and anchor to shift to a direction that is perpendicular to the suture and apposes the meniscal tear. It would have been obvious to modify the method taught by Sikora'649 as taught by Bojarski'694 with a single suture that is attached by its terminal ends to a retaining head and anchor in order to create tension in the two anchors only by placing the terminal ends apart because this allows the surgeon to automatically tighten the suture without the need for the surgeon to additionally agitate and access the surgical site.

12. Sikora'649 does not teach that the retaining head and anchor are attached by the terminal end of the flexible member.

13. The two anchoring elements (11a, 11b) are each connected to a terminal end of a suture (15). The sutures are then tied together, which connects the two device together which connects the two members by a terminal end of a suture (column 4, lines 3-34) in order to create tension in the suture and pull the torn tissue together. It would have been obvious to one skilled in the art at the time the invention was made to modify

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the method taught by Sikora'649 by connecting the two sutures in order to create a tension in the suture that brings the two side of the tissue tear together.

14. Regarding Claim 22, Sikora'649 teaches that the flexible member (1016) is taught between the anchor (1014) and the retaining head (1012) (paragraph [0153]).

15. Regarding Claim 23, Sikora'649 teaches advancing a plunger (1080) within the needle (1070) towards a distal opening of the needle (direction A, Figure 20), deploying the retaining head (1012) from the distal opening and removing the needle (1070) from the body tissue (paragraph [0152]).

16. Regarding Claim 24, Sikora'649 teaches a slit (1076) and attaching the flexible member to an appendage of anchor that protrudes through the slit and holding it while releasing the anchor (paragraph [0146]).

17. Regarding Claim 25, Sikora'649 teaches that advancing the anchor includes advancing a plunger within the hollow tube a predetermined distance t to advance anchor (1014) to a desired location (paragraph [0153]).

18. Regarding Claim 26, Sikora'649 teaches that the first portion of the body tissue is a first outer surface of the meniscus (paragraph [0151], Figure 20).

19. Regarding Claim 27, Sikora'649 teaches a method of repairing a tear in a meniscus that includes inserting a cannulated piercing member (1070) containing a retaining head (1012) therein from a first insertion position on a first outer surface of the meniscus through the tear (1052) and to a second outer surface of the meniscus (1058) (paragraph [0151]), where the retaining head (1012) has a longitudinal body and is positioned longitudinally within the cannulated piercing member (1070) (paragraph

[0015]); ejecting the retaining head (1012) from the piercing member (1070) so that the head engages with the second outer surface (1058) (paragraph [0152]); and advancing an anchor (1014) coupled to retaining head (1012) from a second insertion position (1060b) on the first outer surface of the meniscus to an implanted position (at side 1058), wherein when in the implanted position (at side 1058) the anchor passes through a portion of the tear (1052); further the anchor (1014) is coupled to the retaining head (1012) (paragraph [0005]) that extends a distance along the first outer surface of the meniscus (Figure 20, paragraph [0153]).

20. Sikora'649 does not teach that the anchor is placed between the tear and the outer portion of the body tissue. Further, Sikora'649 does not teach that the retaining head and anchor are attached by the terminal end of the flexible member.

21. Oberlander'462 teaches that an anchor (11b) is placed within the body tissue (31) in a location that is between a tear (31d) and an outer portion of the body tissue (31b) (see Figures 5, 8 and 9) because this is said to enhance the repair of the body tissue since the anchor (11b) is implanted in the thicker part of the tissue (column 4, lines 3-34). It would have been obvious to one skilled in the art at the time the invention was made to modify the method taught by Sikora'649 by placing the anchor between the tear and the outside of the body tissue because placing the anchor within the body tissue aids in enhancing the effectiveness of the repair.

Bojarski'694 teaches that it is known in a method of repairing a meniscus to have a retaining head (1005) and an anchor (1010) that are attached at the terminal ends of a suture (1097) because it allows the surgeon to create tension in the suture by placing

the retaining head and anchor a certain distance apart (paragraph [0151]-[0155]). This tension also causes the retaining head and anchor to shift to a direction that is perpendicular to the suture and apposes the meniscal tear. It would have been obvious to modify the method taught by Sikora'649 as taught by Bojarski'694 with a single suture that is attached by its terminal ends to a retaining head and anchor in order to create tension in the two anchors only by placing the terminal ends apart because this allows the surgeon to automatically tighten the suture without the need for the surgeon to additionally agitate and access the surgical site.

22. Regarding Claim 28, Sikora'649 teaches that ejecting the retaining head (1012) from the piercing member (1070) includes advancing a plunger (1080) within the piercing member (1070) towards a distal opening (1074) of the piercing member (1070); deploying the retaining head from the distal opening (1074) and removing the piercing member from the meniscus at the first insertion position (paragraph [0152]).

23. Regarding Claim 29, Sikora'649 teaches a slit (1076) and attaching the flexible member to an appendage of anchor that protrudes through the slit and holding it while releasing the anchor (paragraph [0146]).

24. Regarding Claim 30, Sikora'649 teaches advancing the anchor includes advancing a plunger within the hollow tube a predetermined distance towards the distal end in order to advance anchor (1014) to a desired location in the meniscus (paragraph [0153]).

25. Regarding Claim 31, Sikora'649 teaches locating the distal end of the hollow tube (1070) a predetermined offset position (1060b) a predetermined offset position from the

said first insertion position (1060a) and advancing the anchor to the desired location provides a taught flexible member between the first and second insertion positions to close the tear (paragraph [0153]).

27. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sikora'649 and Oberlander'462 and Bojarski'694, as applied to Claim 30, in further view of Richards, et al. (US Patent 4,669,473).

28. Sikora'649 and Oberlander'462 and Bojarski'694 teach the limitations of Claim 32, except for connecting the piercing member and hollow tube in order to deploy the retaining head and anchor simultaneously.

29. Richards'473 teaches that it is known to connect a piercing member (405) and a hollow tube (406) via a cross-bar (443) in order to align the front tips of the piercing member and the hollow tube (column 7, lines 55-64). It would have been obvious to one skilled in the art at the time the invention was made to modify the device used in the method taught by Sikora'649 and Oberlander'462 and Bojarski'694 as taught by Richards'473 by connecting the piercing member and hollow tube so that the tips are aligned.

Conclusion

30. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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31. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

32. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lindsey Bachman whose telephone number is 571-272-6208. The examiner can normally be reached on Monday to Thursday 7:30 am to 5 pm, and alternating Fridays.

33. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on 571-272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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34. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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A handwritten signature in black ink, appearing to read "M. J. Hayes", is written in a cursive style.

MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER